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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,742	05/01/2001	Wolfgang Pieken	PRO.03	3461
25871	7590	12/17/2003	EXAMINER	
SWANSON & BRATSCHUN L.L.C. 1745 SHEA CENTER DRIVE SUITE 330 HIGHLANDS RANCH, CO 80129			RILEY, JEZIA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,742

Applicant(s)

PIEKEN ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-18 and 21 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 19 and 20 is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I is acknowledged. Upon further review and comments of applicants, species election for the diene and dienophile has been withdrawn. Therefore the instant claims have been examined for the species of the molecule being a biomolecule and the biomolecule being an oligonucleotide. With respect to instant claims 9, 10, 19, and 20, the species election has been withdrawn, all dienes and dienophiles as claimed, have been examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 11, 12, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the first 4 compounds as claimed in claim 11 does not reasonably provide enablement for the last 2 compounds of instant claim 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There is no disclosure of preparing said compounds comprising 2 or 3 X moieties, attached to the sugar rings, X being a diene, dienophile, 1,3-dipole, etc. (see claim 11). There is no disclosure of compounds comprising a diene and a dienophile attached to the same position in the sugar ring or even attached to different positions in the ribose ring. Therefore someone of ordinary skill in art would not be able to

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synthesize said compounds based on the examples of the instant specification because the specification only discloses example where only one X is attached to either the ribose moiety or the 5'-position.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-8, 11-18, 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Pieken et al. (5,874,532).

Pieken discloses method for the sequential solution phase synthesis of oligonucleotides and peptides. The method lends itself to automation and is ideally suited for large scale manufacture oligonucleotides with high efficiency. Pieken et al.

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describe methods for the sequential solution phase synthesis of oligonucleotides that increase reaction yields and allow for scale-up possibilities. As opposed to traditional schemes in which the 3'-end of the growing oligonucleotide is bound to a solid support, the present invention is characterized by use of an anchor group attached to the 5'-end of the growing oligonucleotide that allows successfully coupled product to be separated from unreacted starting materials. In one embodiment, the anchor group also serves as the 5'-OH protecting group and the coupling reaction occurs in solution. The successfully reacted oligomer will contain the protecting group, while the unreacted oligomer will not, and the materials can be partitioned based on the presence of the anchor/protecting group. In a preferred embodiment, the anchor group reacts covalently with a derivatized solid support, such as a resin, membrane or polymer. In the most preferred embodiment, the monomer unit consists of a 5'-protected phosphoramidite or H-phosphonate, wherein the protecting group is a substituted trityl group, levulinic acid group or silyl ether group. The preferred substitution on the protecting group is a diene functionality, which can react, via a Diels-Alder reaction, with a solid support, such as a resin, membrane or polymer that has been derivatized with a dienophile. In this embodiment, the unreacted oligonucleotide starting material is separated from the reacted nucleotide product based on the selective or specific covalent reaction of the 5'-protecting group with a derivatized resin.

FIG. 7 illustrates graphically the Diels-Alder capture data for the reaction of 5'-DHDTO--T-[3',3']-T--OSiPDBT-5' with polystyrene maleimide resins (col. 9-14, and examples).

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Instant claims 6 and 7 are also rejected, because, even though they define what DDM is, they do not further limit instant claim 4.

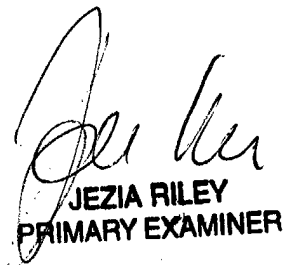
6. Claims 9, 10, 19, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Monday, December 15, 2003


JEZIA RILEY
PRIMARY EXAMINER